

## SPLIMAGE Questions and Answers

Federal Register Notice (Vol. 76, No. 99, FR Doc. 2011–12629, <http://www.gpo.gov/fdsys/pkg/FR-2011-05-23/html/2011-12629.htm> ),

- **How can my company participate?**

Manufacturers may [still] submit products for imaging.

- Send an email to [pillbox@mail.nih.gov](mailto:pillbox@mail.nih.gov) . Include, within the body or subject of the e-mail, “To the attention of Terry Yoo [HPCC]”.

Include in the body of the e-mail your intent to participate in this program. You do not need to provide any information related to products which will be submitted in this announcement of intent. This initial communication is strictly to express intent and to allow for resource allocation planning.

- **Are you still accepting samples for image photography?**

Yes. Samples are still being accepted and photographs will be provided for the duration of the testing period, which is anticipated to continue through FY2012.

- **How should products be provided?**

Select and ship the smallest volume stock package(s) totaling at least 8-10 representative solid oral dosage form medications (e.g., tablets, capsules) of the same drug product.

- The expiration date on the submitted products' packaging should be the longest available
- Include the accompanying prescribing information.
- Consolidated shipments of multiple packages are permitted.
- If there is an undue financial burden associated with providing the smallest volume stock package, please contact NLM via e-mail to [pillbox@mail.nih.gov](mailto:pillbox@mail.nih.gov). Include, within the body or subject of the e-mail, “To the attention of Terry Yoo [HPCC]”.
- Provide contact information for the person(s) submitting the solid oral dosage form medications and receiving the final images. Contact information should include:
  - Firm's name and address.
  - Name, e-mail address, and telephone number of the person submitting the representative solid oral dosage form medications.
  - Name, e-mail address, and telephone number of the person who is responsible for receiving the final images of the representative solid oral dosage form medications.

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*If you have additional questions to add to this document, please send to [theresa.m.brunone@gsk.com](mailto:theresa.m.brunone@gsk.com), or posted against the SPL Working Group WIKI <http://spl-work-group.wikispaces.com/>*

- **Where do I send samples?**

Send the representative solid oral dosage form medications to:

NLM PILLBOX IMAGING PROJECT, Attn: Staff Pharmacist  
2094 Gaither Rd.  
Suite 240, Room 245,  
Rockville, MD 20850.

- **How will my samples be handled after NLM receives them?**

NLM, in collaboration with FDA, has set up a photography laboratory at an FDA facility in Rockville, Maryland for the purpose of generating standardized images of representative solid oral dosage form medications for the duration of this project. This facility is registered with the Drug Enforcement Administration.

- **How will my samples be photographed after NLM receives them?**

**Will they be x-rayed?**

**Will they be scanned using ultraviolet and/or infrared technologies?**

**Will they be assayed using chemical or physical tests?**

The image will encompass visible spectrum only. Ultra-violet and infrared images will not be captured.

No physical or chemical tests or assays of any nature will be performed on the submitted products.

- **Will my samples be kept after NLM photographs them?**

NLM will engage a licensed and qualified service to dispose of all samples. NLM and its contractors will retain accurate records showing what inventory is being retained by the project and what samples have been destroyed."

- **If one of my SPLIMAGE samples has been discontinued, or the product data elements have changed, how difficult would it be to get another SPLIMAGE?**

Currently, the process follows the Federal Register notice.

- **How will I obtain the images of my products?**

The final image file [or a link to that file or a CD] will be sent to the specified e-mail address of the person who is responsible for receiving the final image. SPLIMAGE files are also available directly from an secure NLM online archive. Please contact Dr. [Terry Yoo](#) at HPCC for more information and login access.

- **Can I submit -- using the current SPL submission process -- images that have been created using the SPLIMAGE specification but not provided by NLM?**

At present, the FDA drug listing validation rule concerning the SPLIMAGE element does not specify that the image file must have been produced and/or provided by NLM.

- **For files from NLM, which image(s) can I submit to the FDA? How do I submit the image(s) of my products?**

NLM will provide an image suitable for submission to FDA as part of drug listing for any actively marketed solid oral dosage form medication that is sent to them.

The manufacturer, repackager, or private label distributor may voluntarily include the provided image in an SPL drug listing submission to FDA, in the SPLIMAGE data element. Images submitted as part of the SPL are transmitted to DailyMed by the FDA. These images, provided by NLM or other sources, will be included in the production version of Pillbox.

- **What will NLM do with the images received from sponsors in the SPL files submitted to the FDA and transmitted to the DailyMed site?**

One example: NLM may also use the images it produces to populate the offline version of Pillbox to further agency research and development.

- **What will happen to the SPLIMAGE if the product is discontinued or withdrawn, and is now off the market?**

The SPL file continues to be displayed until a Market End Date is reached. Upon that date, the SPL file is removed from the active area of DailyMed. The SPL file is still available from the [archival section](#) of DailyMed.

- **Is NLM creating both a high and low resolution image with the low resolution image delivered to the product sponsor for inclusion in the SPL?**

Although there are high-resolution images captured and available from the NLM for products imaged as part of this program. SPLIMAGE files are only generated at the resolution published in the SPLIMAGE specification.

- **Will NLM link the submitted SPL to the high resolution image on the NLM website?**

High resolution images that are captured of all the SODF specimens are available through an online NLM archive. That online archive links the SPLIMAGE files with the high-resolution images used to generate the specified file.

**FOR FURTHER INFORMATION CONTACT:**

Any question regarding this process, including alternative methods for receiving the images, should be sent to [pillbox@mail.nih.gov](mailto:pillbox@mail.nih.gov) . Address the e-mail to the attention of Terry Yoo [HPCC].

Any questions regarding submission of the file to FDA should be sent to [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov) .

Any questions regarding the FDA drug listing process should be sent to [edrls@fda.hha.gov](mailto:edrls@fda.hha.gov) .

Any questions about the PILLBOX project should be sent to [pillbox@mail.nih.gov](mailto:pillbox@mail.nih.gov) . Address the e-mail to the attention of David Hale [Project Manager, PILLBOX].

Any questions about DailyMed, complete this [form](#). If your browser does not work with forms, you can send your e-mail directly to [custserv.nlm.nih.gov](mailto:custserv.nlm.nih.gov) .